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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,898	01/18/2002	Wolfgang A. Renner	1700.0190005/BJD/SJE	7794

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EXAMINER	
SALVOZA, M FRANCO G	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,898	RENNER ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/18/2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

jfl

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-50, 52, drawn to a composition comprising a non-molecular scaffold comprising a core particle and an organizer, classified in class 424, subclass 278.1. If this group is elected, election of species is further required.

II. Claim 51, drawn to a method of immunization, classified in class 424, subclass 278.1.

III. Claim 53, drawn to a process for producing an array, classified in class 435, subclass 317.1.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case methods of immunization can use other compositions other than the one cited. Conversely, the composition as claimed can be used for other materially different processes other than mere administration of the composition for immunization purposes.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by other materially different processes. Conversely the methods of immunization can be performed using materially different products other than the one claimed.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are materially different. Producing a molecular antigen array is materially different than immunizing a subject with the claimed compound.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

Election of species within Group I (composition)

If Group I is chosen, further restriction is required under 35 U.S.C. 121 in Claim 1 of:

A. A non-natural molecular scaffold comprising a core particle and an organizer. If this group is elected, election of species is further required.

B. An antigen or antigenic determinant. If this group is elected, election of species is further required.

The inventions are distinct, each from the other because of the following reasons: the scaffold comprising a core particle and an organizer is seen as patentably distinct

from an antigen or antigenic determinant, since the inventions are different structurally and functionally. The scaffold comprises a core particle that includes a group of vectors such as a phage, virus or virus-like particle. The antigen or antigenic determinant has a different function to induce an immune response.

Because these inventions are distinct for the reasons given above and the search required for Group A is not required for Group B, restriction for examination purposes as indicated is proper.

Election of species within Group A (core particle)

If the core particle of Group A is chosen, further restriction is required under 35 U.S.C. 121 in Claims 5 and 28:

1. A virus, a virus like particle, a bacteriophage, a viral capsid particle, or a recombinant form of (1). If this group is elected, election of species is further required.
2. A bacterial pilus or a recombinant form of (2). If this group is elected, election of species is further required.

Inventions 1 and 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions possess different structures and serve different functions. A virus or bacteriophage consists of nucleic acids combined with structural proteins to transmit genomic material into a target cell. However, bacterial pili are

extracellular structures of made of proteins that serve structural purposes of attachment and locomotion.

Election of species within Group 1 (virus, virus-like particle, etc.)

If Group 1 is chosen, further restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 14:

the amino acid sequence of SEQ ID NO: 89

the amino acid sequence of SEQ ID NO: 90

the amino acid sequence of SEQ ID NO: 93

the amino acid sequence of SEQ ID NO: 98

the amino acid sequence of SEQ ID NO: 99

the amino acid sequence of SEQ ID NO: 102

the amino acid sequence of SEQ ID NO: 104

the amino acid sequence of SEQ ID NO: 105

the amino acid sequence of SEQ ID NO: 106

the amino acid sequence of SEQ ID NO: 119

the amino acid sequence of SEQ ID NO: 120

the amino acid sequence of SEQ ID NO: 123

the amino acid sequence of SEQ ID NO: 125

the amino acid sequence of SEQ ID NO: 131

the amino acid sequence of SEQ ID NO: 132

the amino acid sequence of SEQ ID NO: 134

the amino acid sequence of SEQ ID NO: 157

the amino acid sequence of SEQ ID NO: 158

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* (MPEP § 803.04).

...

If Group 1 is chosen, restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 23:

Recombinant proteins of Hepatitis B virus

Recombinant proteins of Measles virus

Recombinant proteins of Sindbis birus

Recombinant proteins of Rotavirus

Recombinant proteins of Foot-and-Mouth-Disease virus

Recombinant proteins of Retrovirus

Recombinant proteins of Norwalk virus

Recombinant proteins of Alphavirus

Recombinant proteins of Human Papilloma virus

Recombinant proteins of Polyoma virus

Recombinant proteins of Bacteriophages

Recombinant proteins of RNA-phages

Recombinant proteins of Qβ-phage

Recombinant proteins of GA-phage

Recombinant proteins of Fr-phage

Recombinant proteins of GA-phage

Recombinant proteins of Ty

The species of recombinant proteins are patentably distinct because the proteins do not share common structure with the other species.

...

If Group 1 is chosen, restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 25:

Bacteriophage Qβ

Bacteriophage R17

Bacteriophage Fr

Bacteriophage GA

Bacteriophage SP

Bacteriophage MS2

Bacteriophage M11

Bacteriophage MX1

Bacteriophage NL95

Bacteriophage F2

Bacteriophage PP7

The species of bacteriophages are seen as patentably distinct because none of the species share common structure with the other species.

...

If Group 1 is chosen, restriction to one of the following groups is also required under 35 U.S.C. 121 in Claim 35:

a. CGG; (G)kC(G)n with n=0-12 and k=0-5; (G)kC(G)m(S)t(GGGGS)n with n=0-3, j=0-5, m=0-10, l=0-2; GGC; GGC-NH2; GnCGk with n=0-12 and k=0-5; GmStGGGGSnG0CGk with n=0-3, k=0-5, m=0-10, l=0-2 and o=0-8

b. N-terminal gamma 1-linker; N-terminal gamma 3-linker; N-terminal glycine linkers; N-terminal glycine serine linkers

c. C-terminal gamma 1-linker; C-terminal gamma 3-linker; C-terminal glycine linkers; C-terminal glycine-serine linkers

c. Ig hinge regions

The groups of amino acid linkers are seen as patentably distinct because none of the groups share a common structure with the other groups.

Election of species within Group B (antigenic or antigenic determinant)

If Group B is chosen, restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 36:

Aβ 1-15; Aβ 1-27

Aβ 1-40; Aβ 1-42

Aβ 33-40; Aβ 33-42

The species of amyloid beta peptide are seen as patentably distinct because the none of the species share a common structure with the other species.

...

If Group B is chosen, restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 37:

SMPH

Sulfo-MBS; Sulfo GMBS

The species of heterobifunctional cross-linkers are seen as patentably distinct because the none of the species share a common structure with the other species.

...

If Group B is chosen, restriction to one of the following species is also required under 35 U.S.C. 121 in Claim 38:

The amino acid sequence of DAEFRHDSGYEVHHQGGC

The amino acid sequence of CGHGNKSGLMVGGVVIA

The amino acid sequence of

DAEFRHDSGYEVHHQKLVFFAEDVGSNGGC

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* (MPEP §803.04).

Since these sequences code for different proteins and independent and distinct inventions, claim 6 is subject to a restriction requirement. While the MPEP §803.04 states that normally at least ten sequences constitute a reasonable number for examination purposes, the Office is moving away from that practice making the claim subject to restriction.

...

If Group B is chosen, restriction to one of the following groups is also required under 35 U.S.C. 121 in Claim 39:

1. A virus-like particle comprising, alternatively consisting of, recombinant proteins, or fragments thereof of bacteriophage Qβ; A virus-like particle comprising, alternatively consisting of, recombinant proteins, or fragments thereof of bacteriophage fr; A virus-like particle of HbcAg-lys-2cys-Mut
2. A bacterial pilus; A Type-1 pilus of Escherichia coli

Inventions 1 and 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions serve different functions. A virus or bacteriophage consists of nucleic acids combined with structural proteins to transmit genomic material into a target cell. However, bacterial pili are extracellular structures of made of proteins that serve structural purposes of attachment and locomotion.

...

If Group B is chosen, restriction to one of the following groups is also required under 35 U.S.C. 121 in Claim 48:

A. CGG; (G)kC(G)n with n=0-12 and k=0-5; (G)kC(G)m(S)t(GGGGS)n with n=0-3, j=0-5, m=0-10, l=0-2; GGC; GGC-NH2; GnCGk with n=0-12 and k=0-5; GmStGGGGSnG0CGk with n=0-3, k=0-5, m=0-10, l=0-2 and o=0-8

B. N-terminal gamma 1-linker; N-terminal gamma 3-linker; N-terminal glycine linkers; N-terminal glycine serine linkers; C-terminal gamma 1-linker; C-terminal gamma 3-linker; C-terminal glycine linkers; C-terminal glycine-serine linkers

C. Ig hinge regions

The groups of amino acid linkers are seen as patentably distinct because none of the groups share a common structure with the other groups.

...

If Group B is chosen, restriction to one of the following groups is also required under 35 U.S.C. 121 in Claim 49:

CGG

CGKR

CGHGNKS

GGC; GGC-NH2

The species of amino acid linkers are seen as patentably distinct because the none of the species share a common structure with the other species.

...

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Sequence Rules

Applicant should review the specification and claims for compliance with the Sequence Rules, particulalîy 37 CFR 1.82 1(d) which requires reference to a SEQ I.D number wherever a sequence is discussed in the specification and claims. It is noted that numerous sequences appear without a SEQ ID number, for example in claim 38. Applicant is required to review the entire disclosure for compliance with the sequence rules, to amend the specification, and to submit a replacement Sequence Listing if all of the disclosed sequences are not already included in the Listing.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached at (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza

Patent Examiner

Jim Housel

Supervisory Primary Examiner

Art Unit 1648

3/21/05